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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,633	07/17/2003	Marc Long	HO-P02125US1	1856
37983	7590	04/29/2005	EXAMINER	
SMITH & NEPHEW, INC. 1450 E. BROOKS ROAD MEMPHIS, TN 38116			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/621,633

Applicant(s)

LONG ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for reconsideration and remarks filed 01/26/05. Claims 58-95 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claims 58-95 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicants' persuasive argument.
2. Claims 76-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 76-78 recite the limitation "particles" in line 1. Claims 76-78 depend from claim 58 and there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 58, 59, 62-75, 86-89 and 93-95 remain rejected under 35 U.S.C. 102(b) as being anticipated by Randolph et al. (US 5,614,206).

Applicants argue that Randolph does not teach dry powder compaction method and that the pellets are formed by hydrated process and not formed through a dry process; applicants further argue that pellets are defined small rounded, spherical or cylindrical body and are thus not of intricate shape.

6. Applicants' arguments filed 01/26/05 have been fully considered but they are not persuasive.

A cylindrical shape in the broadest term is intricate. The claim 58 is directed to a product and how the product is made is not critical to the product. Thus the prior art does not have to disclose the method of "dry powder compacting." Claim 87 does not further define the product, but the claim is rather defining the process of making the product, and thus the claim is examined as a composition/product claim. The same is true for claim 88. In this respect, Randolph teaches all the elements of the claims.

7. Claims 58, 59, 63-66, 86-89 and 93-95 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al. (US 5,981,828).

Applicants argue that the process of making the acetabular cup in Nelson is a wet process because the process requires cement while the instant claims are directed to intricately shaped bone graft that is prepared by dry powder compaction.

Applicants further state that Nelson does not teach all the elements of the pending claims, and claims 87-95 in particular.

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8. Applicants' arguments filed 01/26/05 have been fully considered but they are not persuasive.

The claims are directed to a product and how the product is made does not carry patentable weight. Claim 87 does not further define the product, but the claim is rather defining the process of making the product, and thus the claim is examined as a composition/product claim. The same is true for claim 88. Acetabular cup reads on "intricately shaped." It is respectfully noted that dependent claims 59 and 66 state that the bone material is ceramic. In this respect, Nelson teaches all the elements of the claims.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10. Claims 58-62, 65-71, 73 and 83-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (US 6,296,667).

Johnson discloses bone substitute material that comprises continuous framework structure having struts defining interstices that interconnect throughout the bulk volume; ceramic or osteoconductive material occupy at least a portion of the framework structure and the article includes materials that foster bone in-growth (abstract; column 2, lines 55-67; column 3, lines 18-67; column 4, lines 1-32; column 6, lines 33-67), voids in the framework includes 3-D continuous network of calcium phosphate (column 7, lines 1-7). Johnson's bone substitute reads on intricate structure and because the claims are directed to a product, the process of making the product is not critical. Osteoinductive substances such as bone morphogenic proteins, demineralized bone matrix, transforming growth factors and osteoblast cells; and osteoconductive materials such as fluoroapatite,

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hydroxyapatite and tricalcium phosphate are materials that may be incorporated in the supporting framework of Johnson (column 6, lines 13-32). The article also comprises bioresorbable polymer such as collagen, polylactic acid, polyglycolic acid, gelatin or chitosan (column 3, lines 30-38).

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 76-78 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (US 5,614,206).

Applicants argue that there is no suggestion for intricately shaped bone graft substitute and that “Randolph is silent on the shape the powder is compressed into, other than a pellet.” Applicants assert that there is no suggestion to modify and that it is incumbent on the Examiner to identify some suggestion in the prior art to make the modification from a pellet to intricately shaped substitute.

Applicants state that Randolph teaches away from the invention by disclosing a wet method while the instant process is a dry method. Furthermore, applicants argue that the claims in Randolph are “directed to mixing powders consisting essentially of the alpha- or beta-calcium sulfate hemihydrate,” and that the Examiner has mistaken “obvious with obvious to try.”

13. Applicants' arguments filed 01/26/05 have been fully considered but they are not persuasive.

The rejection under 35 USC 103 is directed to claims 76-78 where the difference between the prior art and the instant claims is in differences in size of the particles and

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not on modifying the pellet to intricately shaped substitute. Pellet as cited by applicants is small rounded, spherical or cylindrical body and cylindrical shape broadly reads on intricate shape. Since the rejection is not on modification of the structure, no suggestion for structure modification is required in the prior art. Also, examiner respectfully recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, however, the difference between the instant claims and the prior art is one of size and, there is no demonstration by applicants that the sizes recited in the designated claims provide unusual results and in the absence of a showing, the instant claimed sizes in the claims 76-78 is not inventive over the size of the prior art. The instant claims are directed to product and how the product is made is not critical. It is also respectfully noted that the whole disclosure is considered when claims are rejected over prior art. The rejection is not one of obvious to try as stated by applicants but rather art rejection where difference in size alone would not patentably distinguish a claimed invention over a prior art.

14. Claims 90-92 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 5,981,828).

Applicants state that Nelson does not disclose intricately shaped bone graft substitute and that if Nelson were modified to comprise intricately shaped bone graft substitute, Nelson's product would not function as an acetabular bone graft.

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15. Applicants' arguments filed 01/26/05 have been fully considered but they are not persuasive.

The acetabular cup is an intricate shape and no modification is required.

16. Claims 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,296,667).

Johnson is described above. Johnson does not specifically describe the specific structures recited in the designated claims. Specifically, Johnson discloses that the bone substitute can be formed into appropriate configurations for use as bone substitute by several methods (column 10, lines 12-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the bone substitute framework of Johnson. One having ordinary skill in the art would have been motivated to prepare the framework that has the desired configuration for use as desired with the expectation that the bone substitute would serve as the desired supporting structure.

The following prior art of interest cited in the last office action is relevant to applicants claimed invention.

Yamamoto et al. (US 6,187,046) discloses prosthetic bone material that comprises sintered product of calcium phosphate granules having particles size of 100 μm , methylcellulose, hydroxyapatite (abstract; column 3, lines 33-54; column 4, lines 2-10; Examples 1-5, 12, 18, 19, 21 and 22).

Laurencin et al. (US 5,626,861) discloses a method of fabricating 3-D macroporous polymer matrices that are used as bone graft or implant and composites are

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formed from biodegradable and biocompatible polymer and hydroxyapatite, gelatin or agarose or starch or alginate polysaccharide (abstract; column 9, lines 32-38).

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 58-80 and 86-95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,630,153. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the instant claims are directed to a product, the claims state that the product can be made by a dry powder compacting and while the issued claims are directed to process of making the product, one of ordinary skill in the art has the ability use the process to make the product.

Observation:

Pages 2-8 of the remarks have application no. 09/792,681 as the header.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571)

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272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

